



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,399	09/12/2003	Dieter Soll	03818/1200029-US2	8426
7278	7590	09/28/2006	EXAMINER	
DARBY & DARBY P.C. P. O. BOX 5257 NEW YORK, NY 10150-5257			SHAHNAN SHAH, KHATOL S	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 09/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/661,399

Applicant(s)

SOLL, DIETER

Examiner

Khatol S. Shahnan-Shah

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-78 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-78 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-10, 24-28, 32-35, 39-42, 48-50 and 71-76 are drawn to polynucleotides, vectors and host cells, classified in classes 536 and 435, subclasses 23.1, 243 and 320.1.
 - II. Claims 11, 29, 36, 43, and 46 are, drawn to polypeptides, classified in classes 530 subclass 350,
 - III. Claims 12, 30, 37, 44 and 47 are drawn to antibodies, classified in class 424, and subclass 130.1.
 - IV. Claims 13, 31, 38 and 45 are, drawn to antagonists, classified in class 504, subclass 103.
 - V. Claim(s) 14 is drawn to a method of treatment comprising administering a polypeptide classified in class 514, and subclass 2.
 - VI. Claim(s) 15 is drawn to a method of treatment comprising administering a polynucleotide classified in class 514, and subclass 44.
 - VII. Claim(s) 16 is drawn to a method of treatment comprising administering an antagonist classified in class 424, and subclass 278.1.
 - VIII. Claim(s) 17 is drawn to a process of diagnosing a disease comprising detecting polynucleotide classified in class 436, and subclass 94.
 - IX. Claim(s) 18 is drawn to a process of diagnosing a disease comprising detecting polypeptide classified in class 436, and subclass 86.
 - X. Claim(s) 19-20 are drawn to a method of identifying a compound, which inhibits protein classified in class 435, and subclass 15.
 - XI. Claim(s) 21 is drawn to a method for identifying AdT mutants classified in class 435, and subclass 193.
 - XII. Claim(s) 22 is drawn to a method for inducing immune response comprising administering a polypeptide classified in class 424, and subclass 185.1

- XIII. Claim(s) 23 is drawn to a method for inducing immune response comprising administering a polynucleotide classified in class 424, and subclass 94.5.
- XIV. Claim(s) 51-70 are drawn to a method of identifying an agent that blocks translation classified in class 536, and subclass 24.1
- XV. Claim(s) 77-78 are drawn to a process for producing plants classified in class 435, and subclass 410

Additionally Groups I-XV are further restricted according to MPEP 803.4 which recites that nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are deemed to normally constitute independent and distinct inventions. Consequently Applicant is required to select a single nucleotide sequence if selecting DNA claims or a single protein if selecting protein claims.

2. The inventions are distinct, each from the other because of the following reasons:
- Inventions I- IV are distinct because they are drawn to distinct compositions, which are structurally distinct chemical compounds and are unrelated to one another.
- Inventions V - XV are distinct because they are drawn to distinct methods, which differ in method steps and material used.

Invention I drawn to DNA molecules and invention II drawn to proteins are distinct from Groups III-XV since they are products with different structure and biological properties. The protein is made of amino acids whereas the nucleic acid molecule consists of nucleotides. Furthermore method known in the art used to make the polypeptide require different reagents and parameters from the methods of making nucleic acid encoding the protein and the method of making the polypeptide does not require the nucleic acid. For instance, the protein can be made by Merrifield chemical synthesis or affinity chromatography.

Invention III, drawn to antibodies are distinct from Inventions I-II and IV-XV, since they display an inherent affinity, avidity and specificity for a given epitope.

Invention IV, drawn to antagonists are distinct from Inventions I-III and V-XV, since they display a distinct biological activity of interacting with a polypeptide in a manner that inhibits activity of the polypeptide.

Invention V, drawn to a method of treatment with a polypeptide, is distinct from Inventions I-IV and VI-XV, since it requires additional biological reagents and parameters for the detection of efficacy with a polypeptide.

Invention VI, drawn to a method of treatment with DNA, is distinct from Inventions I-V and VII-XV, since it requires additional biological reagents and parameters for the detection of efficacy with DNA.

Invention VII, drawn to a method of treatment with an antagonist, is distinct from Inventions I-VI and VIII-XV, since it requires additional biological reagents and parameters for the detection of efficacy with an antagonist.

Invention VIII, drawn to a process of diagnosing a disease comprising detecting DNA, is distinct from Inventions I-VII and IX-XV, since it requires additional biological reagents and parameters for the detection of DNA in a sample.

Invention IX, drawn to a process of diagnosing a disease comprising detecting protein, is distinct from Inventions I-VIII and X-XV, since it requires additional biological reagents and parameters for the detection of protein in a sample.

Invention X, drawn to a method of identifying compounds, which inhibit a polypeptide, is distinct from Inventions I-IX and XI-XV, since it requires additional

biological reagents and parameters for the detection of compounds, which inhibit a polypeptide.

Invention XI, drawn to a method of identifying AdT mutants, is distinct from Inventions I-X and XII-XV, since it requires additional biological reagents and parameters for the detection of mutants.

Invention XII, drawn to a method of inducing immune response with a protein, is distinct from Inventions I-XI and XIII-XV, since it requires additional biological reagents and parameters for the delivery of the protein and the detection of the resulting immune response.

Invention XIII, drawn to a method of inducing immune response with DAN, is distinct from Inventions I-XII and XIV-XV, since it requires additional biological reagents and parameters for the delivery of the DNA encoding the protein and the detection of the resulting immune response.

Invention XIV, drawn to a method of identifying an agent that blocks translation, is distinct from Inventions I-XIII and XV, since it has a specific mechanism of action in blocking translation.

Invention XV, drawn to producing plants, is distinct from Inventions I- XIV, since they are reproducible living organisms.

3. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper. The several inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches.

4. Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. Applicants are advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during

prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Species Election

7. This application contains claims directed to the following patentably distinct species of
the claimed invention:

a) If applicants elect group XIV there is further election of species:

1a. Please elect one of the species A, B or C subunits from claims 52, 53, 58 and 63.

Applicants are required under 35 U.S.C. 121 to elect disclosed species as set forth above for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 9, 21, 22, 23, 24, 51, 71, and 78 are generic.

Applicants are advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

8. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 (a) of the other invention.

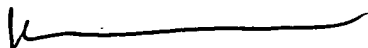
9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is 571-272-0863.

Art Unit: 1645

The examiner can normally be reached on Monday-Friday 7:30 AM-5:00 PM If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Albert (Mark) Navarro can be reached on 571-272-0864.



Khatol Shahnan-Shah . B.S., Pharm, M.S.

Biotechnology Patent Examiner

Art Unit 1645

September 20, 2006



LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER